Incidence and nature of complications following primary repair of Obstetric Anal Sphincter Injury (OASI): retrospective chart review

Original Research Article: original research study

By
Carrie Paulsen
RBRCAR007
MMed III – Minor Dissertation: Obstetrics and Gynaecology
Publication Format
Faculty of Health Sciences
UNIVERSITY OF CAPE TOWN

Supervisor: Dr Kendall Brouard
Co-Supervisor: Dr Gregory Petro

Table of Contents

Declaration

Name: Carrie Paulsen

Student Number: rbrcar007

Course: MMED Obstetrics and Gynecology

Declaration

I know that plagiarism is wrong. Plagiarism is to use another's work and pretend that it is one's own.

I have used the Vancouver convention for citation and referencing. Each contribution to, and quotation in, this essay/report/project/dissertation from the work(s) of other people has been attributed, and has been cited and referenced.

This essay/report/project/dissertation is my own work.

I have not allowed, and will not allow, anyone to copy my work with the intention of passing it off as his or her own work.

Signature Signed by candidate

Date 25/02/2019

Abstract

Background. A multitude of data exists regarding global incidence of OASI as well as its contributing factors and complications. Little to no data exists regarding the incidence of OASI or its complications and the nature of these complications within South Africa.

Objective. To describe the rate and nature of complications of OASI that occur within 6 weeks following primary repair of an OASI, followed up at the GSH perineal clinic. Secondarily, to investigate the incidence of OASI and follow up rate post primary repair

Methods. This was a retrospective chart review. Participants were identified from theatre record books between January 2014 and December 2015. The charts of those that attended the perineal clinic follow up were reviewed and complications and possible associated risk factors were identified from the clinical notes. Primary aims were to identify the incidence and nature of complications seen in this population as well as possible related risk factors. The secondary aims were to determine the incidence of OASI and follow up rate for complication following primary OASI repair.

Results. The mean age of participants was 25.85 years with a mean body mass index of 25.15kg/m^2. The mean birthweight seen was 3382.05 grams. Constipation (10.87%), pain with defaecation (11.96%) and anal incontinence (10.87%) were the most frequently reported complications. Wound infection was found on examination in 3.26% of participants and wound dehiscence was seen in 6.67%. Incidence of OASI in this study group was 8.64 per 1000 vaginal deliveries. The follow up rate of these participants was 26.20%. A total of 374 OASI were repaired within this region during the study period. Only 97 of these attended follow up, for which 93 folders were available to be included in analysis

Conclusion. The Incidence of OASI in this Western Cape region is within the range seen worldwide but the proportion of complications seem to be less than global data suggests despite adverse conditions, theatre delays and the fact that repairs were mostly performed by specialists in training. It was not possible to identify any relationship with possible associated factors. There is a very poor follow up rate within this community which needs to be explored and systems need to be put in place to ensure all participants are given the opportunity of follow up.

Acknowledgements

I would like to thank my supervisor Kendall Brouard for all her support and guidance during the completion of this research.

I would also like to thank Prof. Gregory Petro for all his help and guidance with the statistical analysis for this research.

I would like to acknowledge my husband Kent Paulsen for all of his support during my completion of this project.

List of Figures and Tables

Figures

Tables

CHAPTER 1

1. Introduction

Perineal Injury has been a recognised complication of childbirth since early AD with texts written by Soranus of Ephesus between 98 and 138 AD making reference to perineal care intrapartum.(1) Following this, very little was added to the literature for several centuries. The first written record of complete perineal repair is found in a set of documents written during the 11th century, from the first medical school in Salerno, Italy, known as the Trotula. The writings in the Trotula are based on the teachings of Soranus and severe perineal injury (damage to the anal sphincter complex) is described following lack of perineal support during labour.(1)

1.1 *Incidence and risk factors for OASI*

There is a wide variance in the reported incidence of OASI globally but specific risk factors have been identified across studies including nulliparity, instrumental delivery, large for gestational age infants and midline episiotomy.(2, 3) This incidence is reported between 0.1 and 10.2% with a large study including over 2 million women in California giving an incidence of 5.83% over a 6 year period in the late 1990s.(2, 3) Risk factors can be grouped into maternal, foetal and Obstetric.(4) Most studies agree, reporting similar results regarding the risk inferred by various factors on the incidence of OASI.

The predominant maternal factor reported to increase the risk of OASI is nulliparity, with some studies reporting ethnic descent as a risk factor.(2) Hauck et al from Australia mention Swedish research that shows increased risk of OASI in women of African or Asian descent and conclude from their own study that this is true for women of Indian or Asian descent. The British literature that they reviewed however showed no significant effect of Asian descent on risk of OASI but note that previous Australian data shows that women born in China and Vietnam have increased risk of OASI compared to women born in Australia.(5) The Royal College of Obstetrician and Gynaecologists also note an increased risk of OASI in women of Asian descent(6) but an article by Gundabattula and Surampundi report data from the UK that shows decreased risk of OASI in women of South Asian descent and a systematic review in India that reports the risk of OASI only applies to women of Asian descent living in other Western countries.(7) Handa et al found an association with OASI and Indian ethnicity in their study.(2) There is no firm consensus on the risk of OASI imposed by Asian descent. Some studies noted increased incidence of injury in older women(8) while others found that age and increased BMI have no effect on the rate of injury.(3)

Foetal factors include persistent occipito-posterior position, post term pregnancy and large for gestational age infants, specifically those with birth weight more than 4000g. (2-5, 8) It has been shown that persistent occipito-posterior position is also associated with increased rates of episiotomy, instrumental delivery and caesarean section, some of which are risk factors for OASI themselves.(9)

Obstetric factors that have been reported to increase the risk of OASI include instrumental delivery, use of episiotomy, shoulder dystocia and prolonged second stage. There is no evidence to support superiority of one delivery position over another although water births appear to be associated with lower rates of OASI. It has been suggested this may be related to reduced usage of episiotomy.(9)

It is clear from the data that instrumental delivery is associated with a higher risk of OASI, especially if performed without an episiotomy. It is less clear whether the risk is different for vacuum versus forceps delivery. A study by Sultan et al in 1989 reported a higher incidence of OASI in forceps as compared to Vacuum delivery(10) which correlates with a study in India in 2017(7) as well as data presented by Dudding et al(9). Dudding et al elaborate that most studies showing a more favourable result with vacuum however, do not use endo-anal ultrasound to assess the sphincter, nor do they assess symptoms of anal incontinence.(9) A study in England between 2000 and 2012 also showed increase in OASI in forceps deliveries but the authors mention that as episiotomies were not performed in all of these as per NICE guidelines this may have been a factor that increased the number of injury in this group.(8) Other studies report similar incidences for forceps and vacuum deliveries and some simply assess risk in relation to instrumental delivery without the separation into forceps and vacuum deliveries. (2, 3, 5, 11)

A small study in Israel compared risk of OASI in women following a prolonged second stage of labour either finally delivering spontaneously or by instrumental assistance. The study showed that for every 1 hour that the second stage is prolonged the risk of OASI is increased by 1,5 times and for those that then require instrumental delivery the risk is 2,3 times higher than this.(12)

The use of episiotomy is often motivated by the suggestion that it may be associated with decreased perineal trauma, decreased delivery interval in the case of fetal compromise and facilitation of delivery in the case of shoulder dystocia.(9) It is commonly performed along with instrumental delivery either in the midline or mediolateral position both of which increase the risk of OASI when compared to no episiotomy.(9) A meta- analysis by Sagi-dain et al suggests that assessment of risk of OASI with episiotomy, especially when performed during vacuum delivery, should be stratified by parity as well as type of episiotomy performed.(13) Midline Episiotomy is reported by some studies to increase the incidence of injury and some studies report that mediolateral episiotomy decreases it.(3, 8) The results of the meta-analysis by Sagi-dain agree that median episiotomy is associated with increased risk of OASI but suggest that the risk of OASI with mediolateral episiotomy is related to parity. Their results suggest that while the risk of OASI might be increased when mediolateral episiotomy is used in parous women undergoing vacuum delivery, there is a non-significant decrease in the risk of OASI for nulliparous women undergoing mediolateral episiotomy with vacuum delivery.(13) No significant benefit in terms of neonatal outcome could be shown with episiotomy use for vacuum delivery and in fact increase in maternal complications of postpartum haemorrhage and perineal pain were seen.(13) Handa et al reported a significant protective effect of episiotomy with regard to third degree tears but increased risk of fourth degree tears. They have various explanations for this including avoidance of episiotomy in women in whom tears are expected in order to prevent extension, extension of episiotomies to 4^{th} degree tears and poor documentation of use of episiotomy in women with third degree

tears.(2)Other studies report insufficient data to make a conclusion and judicial use of episiotomy is recommended.(9)

1.2 *Classification and detection of Perineal Injury*

Obstetric anal sphincter injury refers collectively to deep tears of the perineum following childbirth that involve the anal sphincter complex to varying degrees. Sultan(6, 10) developed the following classification system to describe the degrees of perineal trauma. The classification system has been accepted by the Royal College of Obstetricians and Gynaecologists.(6)

- **First degree perineal tear** refers to injury to the perineal skin and/or vaginal mucosa.
- **Second degree tear** involves the perineal muscles but not the anal sphincter.
- **Third degree** tear refers to injury of the anal sphincter complex. Graded:
    - 3a: less than 50% external sphincter thickness
    - 3b: More than 50% external sphincter thickness
    - 3c: External and internal sphincter involved
- **Fourth degree** involves the anal sphincter complex as well as a tear in rectal mucosa.

Clinical examination following vaginal delivery remains the cornerstone for diagnosis of OASI but accuracy has shown to be highly dependent of the training and experience of the examining practitioner. A UK study by Groom et al in 2000 showed that up to 40% of third degree tears are missed by the person performing the delivery.(14) A study by Andrews et al expanded on this and categorised diagnoses missed or made by level of training. It was shown that substantially more tears were missed and incorrectly diagnosed by midwives and house officers than specialist registrars and consultants as compared to the research fellow.(15) This study also showed that true occult injuries are rare with only 3 injuries seen on endo-anal ultrasound, 2 of which involved the internal anal sphincter only, that had no clinical sign of OASI. Skilled clinical examination is therefore accurate at diagnosing OASI but requires training.(15)

1.3*OASI repair*

A superior surgical method of anal sphincter repair has not been established. A Cochrane review done in 2013 analysed 6 randomised controlled trials, which compared overlap repair of the external anal sphincter with end to end repair, and could not conclusively say which method was superior.(16) As the studies included looked at different outcomes, it was difficult to compare the results. It was shown in two studies that in terms of faecal urgency and flatus incontinence, overlap repair had statistically significant less risk than the end to end repair technique over short to medium term although no difference was seen over longer periods of follow up.(16) When looking at faecal incontinence, deterioration of anal incontinence symptoms, perineal pain, dyspareunia and anal incontinence scores no statistically significant differences were found. The Authors concluded that the practitioner should perform overlap or end to end repair at their discretion. They also recommend that further studies are undertaken and that they have predefined follow up periods of 6 weeks, 3, 6 and 12 months with well-defined outcome measures and that they assess quality of life.(16) The Royal College of Obstetrics and Gynaecology Green top guidelines recommend that repair be performed as soon as possible following injury, in an operating theatre with appropriate anaesthesia, lighting and

equipment by a clinician that has been appropriately trained or supervised in repair of Obstetric Anal sphincter injuries.(6) This guideline notes that repair of full thickness external sphincter injuries can be performed with either an overlap or end to end repair with similar outcomes. Internal sphincter injuries and partial thickness external sphincter injuries should be repaired end to end. For rectal mucosa 3.0 polyglactin suture material should be used and the sphincters repaired with either PDS or polyglactin. Following repair they recommend broad spectrum antibiotics and stool softeners in order to aid healing. (6)

1.4 *Complications following OASI repair*

Following OASI and primary repair, various complications are reported including wound breakdown and dehiscence and various degrees of anal incontinence. These can lead to suffering related to perineal pain, sexual dysfunction and social embarrassment, and therefore affect mothers' functioning in their daily lives.(17, 18)

It has been shown that successful primary repair is essential in preventing complications, specifically anal incontinence,(17, 18) however a study by Veronikis et al showed that full thickness rectal wall advancement flap (Noble-Mengert-Fish operation) can be successful in obtaining continence in patients with persistent rectovaginal fistulas and perineal defects even after multiple previous failed repair attempts.(19)

The experience of the person performing the repair seems paramount to the chance of successful repair. A small study in Finland showed that an experienced obstetrician is more likely to affect a successful repair than a midwife or obstetric resident.(20) They also showed that repair during on call hours was more likely to have poor results than those performed during normal working hours. This study reiterated findings published by Nordenstram et al, who performed a randomised controlled trial in Sweden, that compared immediate repair of a third-degree perineal tear to repair that was delayed for at least 8 hours. The study was performed as the authors believed that although delay in repair might be associated with poorer outcomes, immediate repairs would be performed by on call Obstetricians, possibly after hours, with less experience and delayed repairs could be effected by more experienced surgeons. This study showed that a delay of 8-12 hours to repair was not associated with higher rates of anal incontinence or wound complication including infection and abscess formation. (21) This is in contradiction with current RCOG guidelines which advocate for immediate repair and might be informative in developing new guidelines in the future as quality of repair seems to be of more import than timing. In this study all participants received prophylactic antibiotics and the authors report this as a possible reason why no infective complications were seen.(21) Another retrospective cohort study performed in Israel showed that primary repair by an experienced Obstetrician has equivalent results to repair performed by a Colorectal Surgeon. The study was performed under the premise that a Colorectal surgeon would perform superior repair due to superior knowledge of anal anatomy.(22)

The role of prophylactic antibiotics and laxatives with regard to the success of OASI repair is unclear but infection at the repair site may contribute to repair breakdown.(23) Kirss et al report in their study that more patients with successful primary OASI repairs received antibiotics and laxatives after delivery.(20) Duggal et al also performed a small randomised controlled trial which suggests that a single dose of broad spectrum antibiotic (cephalosporin) at the time of

repair significantly reduces the risk of infection and wound breakdown.(23) The most common complications of OASI include wound breakdown, perineal pain, dyspareunia, urinary and anal incontinence.

1.5 *Wound Complications*

Careful follow up of women who sustain obstetric anal sphincter injury has demonstrated a higher rate of wound complications than previously recognized. For example, Lewicky-Gaupp reported that 1/5 women sustain a wound complication typically within 14 days of delivery. (24, 25) Wound dehiscence or breakdown and wound infection are both recognised complications following repair of obstetric anal sphincter injury. Both are significant as poor healing can lead to development of chronic pain, sexual dysfunction, depression, faecal incontinence or fistula formation.(25)

Different risk factors have been identified as being associated with wound complications. Sphincter injury that occurs following operative vaginal delivery is more often associated with wound complications than those that occur during spontaneous delivery. It also appears that the risk of wound complications is higher with forceps deliveries as compared to vacuum.(24, 25)

Other factors that are recognised to be associated with the development of wound complications include increased BMI, deeper tears and smoking.(25, 26) Stock et al did a retrospective folder review to determine risk factors in the antenatal, intrapartum and postpartum period that contribute to development of wound complications following repair of OASI. They agreed that increased body mass index and smoking were significantly associated with poorer wound healing and report that of the number of women who present with either wound infection or breakdown, about half require further surgical repair.(24) They also report higher incidence of wound complication in women colonised by group B streptococcus, women who sustained 4th degree perineal tear, more than 500ml blood loss and interestingly women who were treated with antibiotics in the postpartum period.(24) This is in contrast with reports of other studies where use of prophylactic antibiotics was protective against wound infection and complication. The authors offer two possible explanations for this noting that no antibiotics were given at the time of OASI repair for prophylaxis. The indications for use of antibiotics postpartum were not noted and their first conclusion is that antibiotics were likely administered in order to treat endometritis and thus such a patient would be more susceptible to wound infection. Their second explanation is that antibiotics were administered to patients presenting with perineal wound infection and these were therefore already women at higher risk of developing wound complication.(24)

The role of prophylactic antibiotics remains unclear. A Cochrane review from 2013 aimed to determine the value of prophylactic antibiotic use at the time of anal sphincter injury repair. The authors analysed 6 randomised controlled trials that compared prophylactic antibiotics at repair to placebo, no treatment, treatment with presentation of infection only and different antibiotic regimens.(16) The outcomes of the review were development of local and systemic infection, wound breakdown, patient satisfaction, pain and comfort as well as development of rectovaginal fistula, length of hospital stay, sexual functioning and maternal-infant bonding. There were no statistically significant differences in occurrence of wound complication with the use of antibiotics intrapartum compared with a placebo both on discharge and at follow up

6 weeks postpartum. Unfortunately, they only found one randomised controlled trial that specifically assessed this intervention comparing use of prophylactic antibiotics at time of repair to no antibiotics. Although it was assessed as having a low risk of bias and of good quality, it was terminated before the originally projected sample size was reached with a high rate of loss to follow up.(16) This study by Duggal et al showed that prophylactic antibiotics at the time of repair were significantly associated with reduced wound complications.(23) The paper by Lewicky-Gaupp et al however shows only a small, non-statistical decrease in the incidence of wound complications with prophylactic antibiotics at the time of surgery and reports that any antibiotic use intrapartum for obstetric indications such as Strep B infection or chorioamnionitis is associated with less wound complications likely due to the fact that they are broad spectrum and will treat genitourinary organisms.(25) The Cochrane authors therefore recommend that more research is required. (16)

No definitive benefit of laxatives following repair was demonstrated. (24)The Royal college of Obstetricians and Gynaecologists recommend use of laxatives postoperatively as mentioned above with recommendation level C which usually refers to high quality systematic reviews of case control or cohort studies or well conducted case control or cohort studies.(6) No systematic reviews were found that specifically assessed use of laxatives following repair of OASI but it is thought that hard stool is likely to contribute to dehiscence of the repair and thus stool softeners are recommended by the Royal College of Obstetrician and Gynaecologists. They found one randomised controlled trial which compared laxatives alone to laxatives and stool bulking agents and found no difference in wound complications following repair between the two groups although higher rates of incontinence were found in the group to which a stool bulking agent was added.(6, 27)

The effect of HIV infection on wound healing is not well studied. In a previous small study conducted by a masters' student at the University of Cape Town they aimed to look at the effect of HIV infection on wound healing and functional outcomes following OASI. Although the numbers in the study were small and not statistically significant, this study showed that women infected with HIV tended to have poorer healing, although there was no increased incidence of infection and higher incidence of complications regardless of CD4 count and antiretroviral therapy.(28)

1.6 *Perineal Pain, Dyspareunia and Sexual dysfunction*

Perineal pain postpartum is significantly more common in patients that experienced OASI than those without OASI. It is common for all women to experience some degree of perineal pain postpartum with about 42% experiencing pain immediately following delivery, reducing to 22% and 10% at 8 and 12 weeks postpartum respectively.(29). A prospective cohort study by Andrew et al demonstrated significantly more perineal pain in patients with OASI than those with lesser degree perineal tears or an intact perineum at both 7 to 10 days and 6 to 7 weeks postpartum. They reported similar results to those seen in earlier retrospective studies and mention that women who suffer OASI have higher analgesic use postpartum than those without an OASI.(18)

Dyspareunia is a common finding in postpartum women and severity appears to be related to the degree of perineal trauma experienced but is also influenced by other factors including

breastfeeding and age and instrumental delivery. Previous studies have stated that women with OASI have significantly higher rates of dyspareunia and that this is worse when women are breastfeeding due to the relatively hypo-oestrogenic state they experience.(18) In contrast, a study by Andrews et al showed that the degree of perineal tear had no effect on timing of return to intercourse with 40% of postpartum women being sexually active at 7 weeks and no difference seen between differing degrees of perineal injury. The study agreed that rates of dyspareunia were increased in breastfeeding women, but this finding was not statistically significant. (18) The timing of return to sexual activity is poorly investigated and understood but has been reported to be influenced by degree of perineal injury, maternal age, breastfeeding and ethnic descent.(30) It has been noted that up to 62% of postpartum women experience dyspareunia in the first 3 months following delivery and contrary to the findings of Andrews et al, that the experience is directly related to the degree of perineal trauma.(29) Women with OASI are noted to have a significantly higher chance of experiencing dyspareunia at 3 months postpartum than those without perineal injury.(29, 30) A study by Signarello et al showed that women with intact perineum return to sexual activity faster than those with perineal injury and although most women reported pain on first sexual encounter this was more likely in patients with higher degree perineal tears and that they were more likely to describe more severe pain. This pain does appear to resolve and improve over time but up to 22% of postpartum women continue to experience pain 6 months postpartum with a higher proportion of these having suffered deep perineal tears. The authors also note that pain is more likely to persist and be more severe if an instrumental delivery was performed.(30) Older and non-Caucasian women were also shown to return to intercourse later and as all women in the study were primiparous they state that this is likely due to lifestyle and cultural differences.(30) Instrumental delivery was shown by an Australian study in Melbourne to be more likely to cause more severe degrees of dyspareunia.(31)

Altered sexual function is common in women in the postpartum period. Unfortunately, little data exists with regard to the relationship between perineal or anal sphincter injury and sexual function. Sexual function can be assessed by looking at three parameters: sexual sensation, sexual desire and likelihood to orgasm. It has been found that at 6 months postpartum most women experience sexual difficulties in these areas irrespective of presence, absence or depth of perineal injury.(30, 32)Twenty six percent of all the women also reported being less likely to experience orgasm. Improved sexual functioning in all three areas was more likely to be reported by participants with intact perineum than their counterparts that had suffered perineal injury.(30) Despite the lack of data it appears from these small studies that perineal injury has a significant effect on women's sexual functioning and that the degree and level of injury directly relates to the severity of the deficit that they experience.(29, 30)

1.7 *Anal Incontinence*

Anal incontinence (AI) is the most devastating complication of OASI and is commonly present in women postpartum and resolves over time. It is defined as any involuntary loss of faeces or flatus that adversely affects a woman's quality of life or is a social or hygienic problem. This definition includes urgency of defecation.(33, 34) It is usually assessed in 3 spheres to describe levels of severity. These are incontinence to flatus, incontinence to liquid stool and incontinence to solid stool.(33, 34)

The severity of AI is usually assessed using validated questionnaires. Most of the scoring systems assess frequency of incontinence as well as type of incontinence, either to flatus, liquid or solid stool. Some also include scores for having to make lifestyle changes in order to live with the incontinence. An article by Vaizey et al compared the Pescatori, Wexner and American medical systems score to a new scale developed by the authors and aimed to evaluate their value and reproducibility.(35) It showed that all the scores except the American medical systems score correlated well with clinical evaluation and provide reliable and reproducible scores that can confidently be used in order to assess severity of faecal incontinence and takes into account the effect on quality of life.(35)

More severe symptoms of AI tend to occur following OASI and are more likely to persist. The incidence is reported between 27 and 57% following obstetric anal sphincter injury with larger percentages reported in the smaller study groups.(17, 36-38) In a study by Reid et al which looked at longer term outcome of OASI over 3 years they showed that women who complained of milder symptoms such as faecal urgency or flatus incontinence experienced a significant reduction in symptoms at 3 years as compared to 9 weeks. For women with symptoms of faecal incontinence for liquid or solid stool at 9 weeks, symptoms tended to persist when followed up at 3 years. This was true for all third degree tears with no difference regarding depth or severity of sphincter injury.(36) Fornell et al showed that sphincter function deteriorates over time when they followed up patients over a ten year period and that further vaginal deliveries led to further deterioration in symptoms.(32)

Symptoms of AI are more common following OASI than normal vaginal delivery and caesarean section. Evers et al conducted a study where they compared the incidence of anal incontinence in women who suffered an obstetric anal sphincter injury to those who had a vaginal injury without OASI and women who had caesarean delivery. The overall incidence of women experiencing symptoms of anal incontinence 5-10 years postpartum was reported to be 10%.(39) Their study showed that women with OASI were significantly more likely to report symptoms of anal incontinence as well as lifestyle changes in order to manage these symptoms. Women who had vaginal delivery without OASI and caesarean section showed no difference in likelihood of experiencing symptoms of anal incontinence except flatus incontinence, where this was more likely in women who had vaginal delivery than those who had caesarean section.(39) They also showed that women who suffered OASI following instrumental delivery were most likely to suffer anal incontinence but that in vaginal instrumental delivery without OASI, there was no difference in risk of anal incontinence compared to those who had normal vaginal delivery or caesarean section. They concluded from this study that OASI carries significant risk of anal incontinence 5-10 years post-delivery and that this has significant impact on their quality of life.(39)

2. Study Purpose

Little to no data exists regarding the incidence of Obstetric anal sphincter injury in South Africa. In addition, very little is known with regards to the rate and nature of complications following primary OASI repair in South Africa. This review aims primarily to describe the

incidence and type of complications seen within the first 6 weeks postpartum within a specific Western Cape regions. We also aim to determine the incidence of OASI in this region and identify possible related risk factors that may be associated with complications. This will enable us to gain a better understanding of our local perspective and assess the service being provided to the patients in our setting.

3. References

1. Dahlen HG, Homer CS, Leap N, Tracy SK. From social to surgical: historical perspectives on perineal care during labour and birth. Women Birth. 2011;24(3):105-11.
2. Handa VL DBaGW. Obstetric Anal Sphincter Lacerations. Obstetrics and Gynaecology. 2001;98(2):225-30.
3. Hirayama F, Koyanagi A, Mori R, Zhang J, Souza JP, Gulmezoglu AM. Prevalence and risk factors for third- and fourth-degree perineal lacerations during vaginal delivery: a multi-country study. BJOG. 2012;119(3):340-7.
4. Surampudi S. Risk factors for obstetric anal sphincter injuries (OASI) at a tertiary centre in south India. International Urogynaecology Journal. 2017.
5. Hauck YL, Lewis L, Nathan EA, White C, Doherty DA. Risk factors for severe perineal trauma during vaginal childbirth: a Western Australian retrospective cohort study. Women Birth. 2015;28(1):16-20.
6. Gynaecologists RCoOa. Greentop guideline no 29: Management of Third-and Fourth- degree perineal tears2015. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-29.pdf.
7. Gundabattula S, Surampudi K. Risk factors for obstetric anal sphincter injuries (OASI) at a tertiary centre in south India. International Urogynaecology Journal. 2017.
8. Gurol-Urganci I, Cromwell D, Edozien L, Mahmood T, Adams E, Richmond D, et al. Third- and fourth-degree perineal tears among primiparous women in England between 2000 and 2012: time trends and risk factors. British Journal of Obstetrics and Gynaecology. 2013(120):1516-25.
9. DuddingTC VC, MA K. Obstetric anal sphincter injury: incidence, risk factors and managment. Annals of Surgery. 2008;247(2):224-37.
10. Sultan AH, Kamm MA, Hudson CN, Bartram CI. Third degree obstetric anal sphincter tears: risk factors and outcome of primary repair. BMJ. 1994;308(6933):887-91.
11. Jha S, Parker V. Risk factors for recurrent obstetric anal sphincter injury (rOASI): a systematic review and meta-analysis. Int Urogynecol J. 2016;27(6):849-57.
12. Garmi G, Peretz H, Braverman M, Berkovich I, Molnar R, Salim R. Risk factors for obstetric anal sphincter injury: To prolong or to vacuum? Midwifery. 2016;34(178-182):178-82.
13. Sagi-Dain L SS. Morbidity associated with episiotomy in vacuum delivery: a systematic review and meta-analysis. BJOG. 2015;122:1073-81.
14. Groom KM P-BS. Can we improve on the diagnosis of third-degree tears? European Journal of Obstetrics & Gynecology and Reproductive Biology. 2002;101:19-21.
15. Andrews V SA, Thakar R, Jones P. Occult anal sphincter injuries—myth or reality? BJOG. 2006;113:195-200.
16. Fernando RJ, Sultan AH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. Cochrane Database Syst Rev. 2013(12):CD002866.
17. Marsh F, Lynne R, Christine L, Alison W. Obstetric anal sphincter injury in the UK and its effect on bowel, bladder and sexual function. Eur J Obstet Gynecol Reprod Biol. 2011;154(2):223-7.
18. Andrews V, Thakar R, Sultan A, Jones P. Evaluation of postpartum perineal pain and dyspareunia—A prospective study. European Journal of Obstetrics & Gynecology and Reproductive Biology 2008;137:152-6.
19. Veronikis DK ND, Spino C. The Noble-Mengert-Fish operation—Revisited: A composite approach for persistent rectovaginal fistulas and complex perineal defects. American Journal of Obstetrics and Gynaecology. 1998;179:1411-7.
20. Kirss J, Pinta T, Bockelman C, Victorzon M. Factors predicting a failed primary repair of obstetric anal sphincter injury. Acta Obstet Gynecol Scand. 2016;95(9):1063-9.
21. Nordenstram J, Mellgren A, Altman D, Lopez A, Johansson C, Anzen B, et al. Immediate or delayed repair of obstetric anal sphincter tears-a randomised controlled trial. BJOG. 2008;115(7):857-65.

22. Salima R, Peretz H, Molnar R, Braverman M, Hatokay A, Shalev E. Long-term outcome of obstetric anal sphincter injury repaired by experienced obstetricians. International Journal of Gynecology and Obstetrics 2014;126:130-5.
23. Duggal N MC, Daniels K, Bujor A, Caughey AB, El-Sayed YY. Antibiotic Prophylaxis for Prevention of Postpartum Perineal Wound Complications: A Randomized Controlled Trial. Obstetrics and Gynaecology. 2008;111(6):1268-73.
24. Stock L, Basham E, Gossett DR, Lewicky-Gaupp C. Factors associated with wound complications in women with obstetric anal sphincter injuries (OASIS). Am J Obstet Gynecol. 2013;208(4):327 e1-6.
25. Lewicky-Gaupp C, Leader-Cramer A, Johnson LL, Kenton K, Gossett DR. Wound complications after obstetric anal sphincter injuries. Obstet Gynecol. 2015;125(5):1088-93.
26. Williams MK, Chames MC. Risk factors for the breakdown of perineal laceration repair after vaginal delivery. Am J Obstet Gynecol. 2006;195(3):755-9.
27. Eogan M, Daly L, Behan M, O'Connell PR, O'Herlihy C. Randomised clinical trial of a laxative alone versus a laxative and a bulking agent after primary repair of obstetric anal sphincter injury. BJOG. 2007;114(6):736-40.
28. van den Berg J, Jeffery S. Healing and functional outcomes after obstetric anal sphincter injury in HIV- positive vs HIV-negative patients. 2009.
29. Abdool Z, Thakar R, Sultan AH. Postpartum female sexual function. Eur J Obstet Gynecol Reprod Biol. 2009;145(2):133-7.
30. Signorello LB, Harlow BL, Chekos AK, Repke JT. Postpartum sexual functioning and its relationship to perineal trauma: a retrospective cohort study of primiparous women. Am J Obstet Gynecol. 2001;184(5):881-8; discussion 8-90.
31. McDonald E, Gartland D, Small R, Brown S. Frequency, severity and persistence of postnatal dyspareunia to18 months postpartum: A cohort study. Midwifery. 2016;34:15-20.
32. Fornell EU, Matthiesen L, Sjodahl R, Berg G. Obstetric anal sphincter injury ten years after: subjective and objective long term effects. BJOG. 2005;112(3):312-6.
33. LaCross A, Groff M, Smaldone A. Obstetric anal sphincter injury and anal incontinence following vaginal birth: a systematic review and meta-analysis. J Midwifery Womens Health. 2015;60(1):37-47.
34. Fernando RJ, Sultan AH, Radley S, Jones PW, Johanson RB. Management of obstetric anal sphincter injury: a systematic review & national practice survey. BMC Health Serv Res. 2002;2(1):9.
35. Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. Gut. 1999;44(1):77-80.
36. Reid AJ, Beggs AD, Sultan AH, Roos AM, Thakar R. Outcome of repair of obstetric anal sphincter injuries after three years. Int J Gynaecol Obstet. 2014;127(1):47-50.
37. Nichols C, Lamb E, Ramakrishnan V. Differences in outcomes after third-versus fourth-degree perineal laceration repair: A prospective study. American Journal of Obstetrics and Gynecology 2005;193:530-6.
38. Gjessing H, Backe B, Sahlin Y. Third degree obstetric tears; outcome after primary repair. Acta Obstet Gynecol Scand. 1998;77(7):736-40.
39. Evers EC, Blomquist JL, McDermott KC, Handa VL. Obstetrical anal sphincter laceration and anal incontinence 5-10 years after childbirth. Am J Obstet Gynecol. 2012;207(5):425 e1-6.

CHAPTER 2

Publication Ready Manuscript

4. Cover Letter

Dear Editor in Chief

Please accept the enclosed manuscript **"Incidence and nature of complications following primary repair of Obstetric Anal Sphincter Injury (OASI): Retrospective cross-sectional review".**

Obstetric anal sphincter injury (OASI) is a recognised complication of normal vertex delivery with well researched risk factors. There are also many studies regarding the incidence of OASI and its complications in the international community, however little to no data exists within the South African or even African context. Complications of OASI can be devastating for a woman and it is important that this is recognised and its impact known so that an acceptable service can be provided to these women. As previously unreported data these complications represent a hidden burden of disease associated with childbirth and OASI. This review contains information relevant to the practice of not only general Obstetricians and Gynaecologists but also to General practitioners, nurses, midwives and allied health professionals such as physiotherapists, who may be involved not only with the delivery of these patients but also their follow up care and rehabilitation.

The purpose of this study was primarily to determine the rate and nature of complications seen post primary repair of OASI, but also to determine the incidence of OASI and its follow up rate within the Metro West region of Cape Town at Groote Schuur Hospital.

Our data has not been published or presented elsewhere and the manuscript is not under review at any other journal. We declare no conflict of interest.

Sincerely,

C Paulsen
Department of Obstetrics and Gynaecology

University of Cape Town

Groote Schuur Hospital

Cape Town

South Africa

Title Page

ORIGINAL ARTICLE

Incidence and nature of complications following primary repair of Obstetric Anal Sphincter Injury (OASI): retrospective cross-sectional review

Carrie Paulsen, MBChB, Kendall Brouard, MBChB, FCOG (SA), MMed (UCT), Urogynaecology, Department of Obstetrics and Gynaecology, Groote Schuur Hospital, University of Cape Town, Cape Town, South Africa, Gregory Petro, MBChB, FCOG (SA), Department of Obstetrics and Gynaecology, New Somerset Hospital, University of Cape Town, Cape Town, South Africa.

Corresponding Author: C. Paulsen, Groote Schuur Hospital, University of Cape Town, Main Road, Observatory, Cape Town, 7295, South Africa.

Email: carrierobertson007@gmail.com

Disclosure statement: The authors declare that they have no conflicts of interest and nothing to disclose

Abstract

Background. A multitude of data exists regarding global incidence of OASI as well as its contributing factors and complications. Little to no data exists regarding the incidence of OASI or its complications and the nature of these complications within South Africa.

Objective. To describe the rate and nature of complications of OASI that occur within 6 weeks following primary repair of an OASI, followed up at the GSH perineal clinic. Secondarily, to investigate the incidence of OASI and follow up rate post primary repair

Methods. This was a retrospective chart review. Participants were identified from theatre record books between January 2014 and December 2015. The charts of those that attended the perineal clinic follow up were reviewed and complications and possible associated risk factors were identified from the clinical notes. Primary aims were to identify the incidence and nature of complications seen in this population as well as possible related risk factors. The secondary aims were to determine the incidence of OASI and follow up rate for complication following primary OASI repair.

Results. The mean age of participants was 25.85 years with a mean body mass index of 25.15kg/m^2. The mean birthweight seen was 3382.05 grams. Constipation (10.87%), pain with defaecation (11.96%) and anal incontinence (10.87%) were the most frequently reported complications. Wound infection was found on examination in 3.26% of participants and wound dehiscence was seen in 6.67%. Incidence of OASI in this study group was 8.64 per 1000 vaginal deliveries. The follow up rate of these participants was 26.20%. A total of 374 OASI were repaired within this region during the study period. Only 97 of these attended follow up, for which 93 folders were available to be included in analysis

Conclusion. The Incidence of OASI in this Western Cape region is within the range seen worldwide but the proportion of complications seem to be less than global data suggests despite adverse conditions, theatre delays and the fact that repairs were mostly performed by specialists in training. It was not possible to identify any relationship with possible associated factors. There is a very poor follow up rate within this community which needs to be explored and systems need to be put in place to ensure all participants are given the opportunity of follow up.

PUBLICATION MANUSCRIPT

5. Introduction

Obstetric anal sphincter injury (OASI) refers to deep tears of the perineum following childbirth that involve the anal sphincter complex to varying degrees. The current classification system describing the degree of perineal trauma, was developed by Sultan and accepted by the Royal College of Obstetrics and Gynaecology(RCOG) in 2015. [1]

The reported global incidence of OASI is between 0.1 and 10.2%.[2] Various complications have been reported following OASI and repair, including wound infection, dehiscence and anal incontinence (AI). These can lead to perineal pain, sexual dysfunction and social embarrassment which can affect quality of life and daily function. It has been shown that successful primary repair is essential in preventing complications, specifically AI, and that secondary repair most often has poor long-term outcome.[3,4]

There is very little South African data regarding the incidence of OASI and its complications. A small study was conducted in Cape Town in 2009 investigating the effect of Human Immunodeficiency Virus (HIV) infection on wound healing and functional outcomes following OASI. The results were not statistically significant due to small numbers however, HIV positive women tended to have poorer healing, without an increased incidence of infection. [5] Neither the incidence of OASI nor postoperative complications were investigated.

This review aims to describe the incidence of OASI in a Western Cape region and to explore the complications seen 6 weeks postpartum at the dedicated follow-up clinic.

6. Methods

6.1 Aims:

This study aimed to investigate the rate and nature of complications of OASI that occur within 6 weeks following primary repair of an OASI, followed up at the GSH perineal clinic. Secondarily, to investigate the incidence of OASI and follow up rate post primary repair.

6.2 Objectives:

Primary:

1. Describe the incidence and nature of complications following primary repair of OASI seen within 6 weeks postpartum
2. Identify factors related to the development of complications following primary repair of OASI

Secondary:

1. Determine the incidence of OASI in the Metro West region of Western Cape
2. Determine the follow up rate after primary repair of OASI

6.3 Outcomes

Primary:

1. Anal incontinence
2. Wound dehiscence
3. Wound infection
4. Perineal pain
5. Constipation
6. Factors related to complications

Secondary:

1. Incidence of OASI in Metro West region
2. Follow up rate at GSH perineal clinic

6.4 Patient Population and Setting

GSH is a tertiary hospital serving the people in the Metro West region of the Cape Metropole. Patients are referred from district and regional hospitals within the region. The region is in an urban setting but some of the drainage areas are among the most impoverished areas of South Africa and the Western Cape. The area is characterised by a high unemployment rate, unskilled workers and poor housing with lack of access to basic amenities. Most inhabitants are reliant on public transportation which is notoriously unreliable and unavailable after hours. This region is similar to other urban settings within South Africa. GSH is one of only two tertiary centres in the Western Cape and therefore patients from rural areas on the West Coast of the Western cape also drain there. The issues regarding unemployment and poverty are congruent with the urban areas, only with more difficult access to healthcare due to distance and transportation. GSH has a dedicated perineal clinic, run by the Uro-gynaecology unit, that follows up patients 6 weeks after primary repair of an OASI in one of these hospitals.

According to The Perinatal Problem Identification Program (PIPP) data, 33 777 and 33 556 live births occurred in Metro west region in 2014 and 2015 respectively with 22 023 (65,2%) and 21 247 (63,3%) of these by normal vertex delivery (NVD).[6]

6.5 Participants:

Inclusion criteria

All individuals that had repair of an OASI in theatre in a Metro West region hospital during the study period.

Exclusion criteria

Individuals who sustained an OASI who didn't follow up at the perineal clinic

In cases where the chart was missing, data was only used to calculate the incidence of OASI and rates of complications. Due to the paucity of peripartum information, the data from these

cases could not be used in the identification of risk factors or establishment of association with complications.

6.6 *Study Design:*

This was a retrospective chart review.

In view of the convenience sampling used, a power calculation was performed. The incidence of Anal Incontinence (AI) in the group of patients with OASI was estimated at 11%. The prevalence of AI in the general population (i.e. without OASI) was estimated at 1.4% [7] With a prevalence of 43270 vaginal births and an incidence of 374 OASIs, and using a confidence level of 95%, the power for the study approximates 100%.

Anal incontinence	NVD WITHOUT OASI	OASI	
YES	600 (taken from UK data for population based prevalence of AI = 1.4%)	44 (extrapolated from 10/93 to add up to 374)	
NO	42296	330	
	42896	374 (from our data)	43270 (from PPIP)

Power for Cohort Studies

	Input Data
Two-sided confidence interval (%)	95
Number of exposed	374
Risk of disease among exposed (%)	11
Number of non-exposed	42896
Risk of disease among non-exposed (%)	1.4
Risk ratio detected	7.9

Power based on:	
Normal approximation	100%
Normal approximation with continuity correction	100%

Demographic details are presented on tables and graphs with relevant proportions presented as percentages (%). The tables represent associations with p-values and 95% confidence intervals where appropriate. Continuous numerical data were analysed using t-tests. Categorical data were analysed using chi-square tests and Freidman tests (where there were fewer than 5 subjects). A p-value of less than 0.05 was used to indicate statistical significance for all analyses.

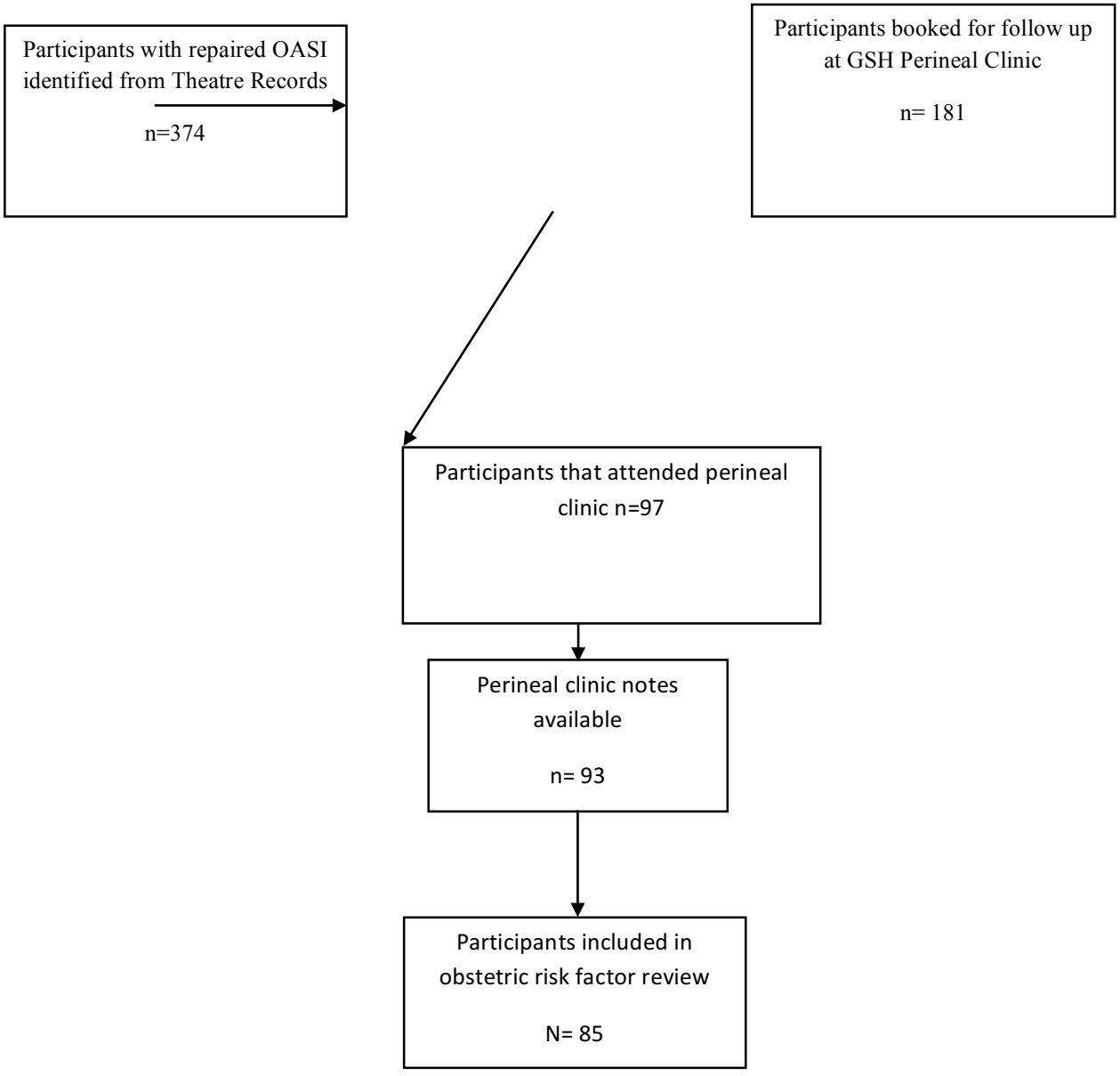
All individuals who sustained an OASI and had it repaired at Mitchells Plain District Hospital (MPH), New Somerset Hospital (NSH), Mowbray Maternity Hospital (MMH) or Groote Schuur Hospital (GSH) Maternity centre were identified from theatre record books for that time period. Based on the GSH electronic booking system, an assessment was made as to whether an appropriate Perineal Clinic appointment was made from the initial institution, as well as whether patients attended these appointments.

The GSH medical records for the participants who attended their 6week Perineal clinic follow-up, were reviewed. Functional outcomes as well as the number and type of complications were noted. No standardised questionnaire was used during the study period, clinical notes were used as a substitute.

The Maternity charts from the hospitals where primary repair was performed. were reviewed Data regarding basic maternal demographics was extracted. Intrapartum details were recorded, including level of experience of birth attendant, the use and type of instruments and birth weight. Any relevant medical conditions were also recorded, including HIV status.

The level of expertise of the repairing surgeon, surgical technique and post op interventions such as antibiotic use, were noted.

Figure I: Review Process



7. Results

7.1Participants Description

Table I: Study Participant Characteristics n=85

	Age	Height (cm)	Weight (kg)	BMI (kg/cm2)	Birthweight(g)
Mean	25.85	159.55	64.06	25.15	3382.05
Minimum	15	148	42	17	2450
Maximum	38	178	119	43	4760
SD	5.24	5.39	13.53	4.95	476.49
Median	25	159	62	25	3400
IQR	8	8	15	5	640

- SD = standard deviation, IQR =Interquartile range

In this study, 65.26% of women were primiparous while 34.74% had delivered previously.

7.2 Incidence of Complications and Associated Factors

Complications were grouped according to those reported in the history and those found on examination. On history, 1 wound infection (1.09%) and 1 dehiscence (1.09%) was reported. Six participants (6.52%) reported dyspareunia in the preceding 6 weeks, although the majority of participants had not yet resumed sexual activity. Some of these had dyspareunia that predated the delivery. Constipation was reported by 10 participants (10.87%) and 11 (11.96%) experienced pain with defaecation.

Table II shows the incidence of symptoms suggesting severity in AI and Table III illustrates the co-existence of the symptoms.

Table II: Incidence of Anal Incontinence

Symptom	n (%)
Gas	8 (8.70)
Liquid Stool	3 (3.33)
Solid Stool	4 (4.35)

Table III: Co-Existence of symptoms of AI

Symptoms of Anal Incontinence	n (%)
Gas only	5 (5.43)
Gas and Liquid stool	1 (1.08)
Gas, Liquid and solid stool	2 (2.17)
Solid stool only	2 (2.17)

Ninety-three participants attended follow up of whom 3 declined examination. Of those examined, 3 had wound infection (3.26%) (only 1 had reported infection and she also complained of pain with defaecation). Six participants had wound dehiscence (6.67%), one of whom complained of complete anal incontinence. Tenderness of the area on exam was demonstrated in 16 participants (17.78%) and 7 had granulomas (7.78%). Decreased squeeze pressure was demonstrated in 10 participants (11.11%), including the 2 who had reported complete anal incontinence. Only one participant (1.11%) had a stricture on examination.

Table IV compares wound dehiscence with antibiotic regimen given. No details were available for two participants. Information regarding antibiotics was available for two of the three participants found to have wound infection on examination, both had received antibiotics intra and postoperatively. Neither of the HIV positive participants had wound infection.

Table IV: Comparison between wound dehiscence and prophylactic antibiotic use (n=88)

Antibiotics	History of wound dehiscence n (%)	Exam finding wound Dehiscence n (%)
Intraoperative only (n=7)	0 (0)	1 (14.29)
Postoperative only (n=4)	0 (0)	0 (0)
Intra- and Postoperative (n=77)	1 (1.30)	4 (5.33)

Table V compares the expertise of surgeon repairing the OASI and incidence of wound dehiscence on examination. Table VI compares repair technique with examination finding of wound dehiscence.

Table V: Comparison between staff category of surgeon and wound dehiscence n=85

Surgeon Level	Wound dehiscence n (%)	% of total wound dehiscence contributed by staff category
Medical Officer (n=7)	1 (14.29)	16.67
Registrar year 1 (n=23)	2 (8.70)	33.33
Registrar year 2 (n=22)	1 (4.55)	16.67
Registrar year 3 (n=10)	1 (10)	16.67
Registrar year 4 (n=23)	0 (0)	0
Consultant (n=1)	1 (100)	16.67

Table VI: Comparison between repair technique and wound dehiscence n=86

Repair Technique	Wound dehiscence n (%)	% of total wound dehiscence contributed by technique
Overlap (n=47)	2 (4.26)	33.33
End to end (n=28)	3 (10.71)	50
Unknown (n=11)	1 (9,09)	16,67

If the unknown category is removed from the above analysis, wound dehiscence contributed by overlap repairs becomes 40% and end to end repairs 60%.

Table VII compares the staff category of surgeon and anal incontinence.

Table VII: Comparison between staff category of surgeon and anal incontinence

Surgeon	AI n (%)	% of total AI contributed by staff category
Medical Officer (n=7)	2 (28.57)	20
Registrar year 1 (n=25)	1 (4)	10
Registrar year 2 (n=22)	2 (9.09)	20
Registrar year 3 (n=10)	2 (20)	20
Registrar year 4 (n=23)	2 (8.7)	20
Consultant (n=1)	1 (100)	11.36

Table VIII Compares repair technique and incidence of anal incontinence.

Table VIII: Comparison between repair technique and anal incontinence

Repair Technique	AI n (%)	% of total AI contributed by technique
Overlap (n=48)	6 (12.50)	60
End to end (n=28)	3 (10.71)	30
Unknown (n=11)	1 (9.09)	10

Table IX compares instrumental delivery and anal incontinence.

Table IX: Comparison between instrumental delivery and anal incontinence

Delivery	AI n (%)	% of total AI contributed by Mode of delivery
NVD (n=72)	7 (9.72)	70
Ventouse (n=12)	2 (16.67)	20
Forceps (n=6)	1 (16.67)	10

*p-value for the above table is 0.704

Figure II shows the site of deliveries (MOU: Midwife lead birthing unit) and Figure III indicates who the birth attendant was. Figure IV indicates distribution of the various modes of delivery.

Figure II: Site of Delivery

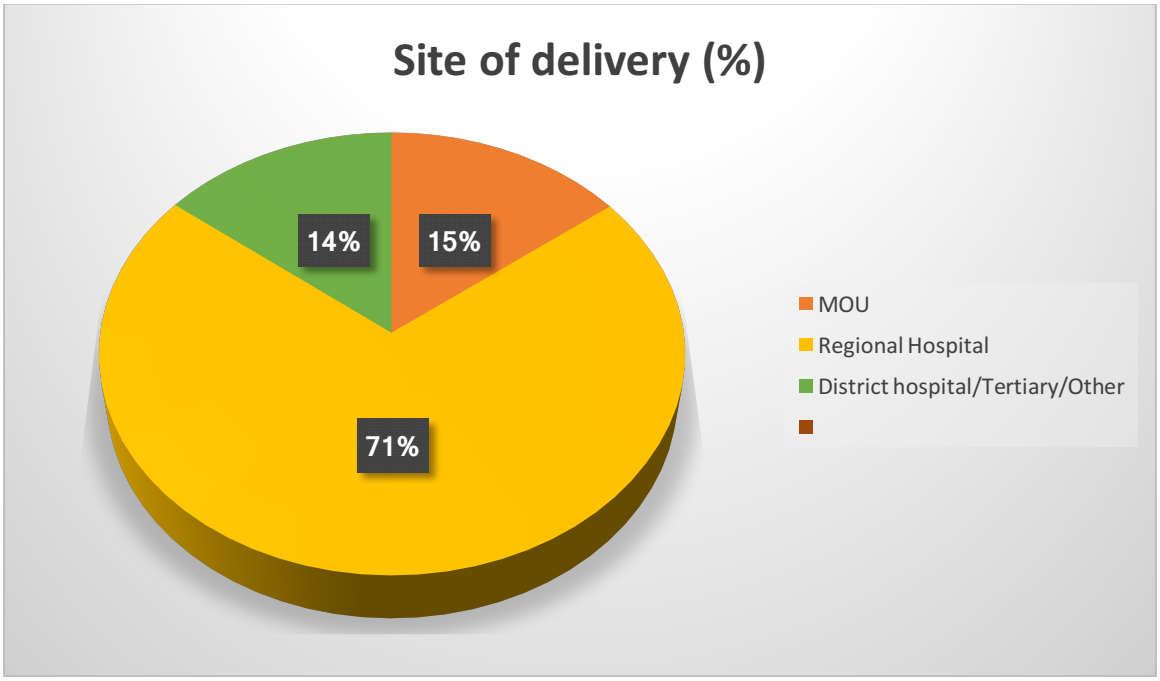


Figure III: Delivery Attendant

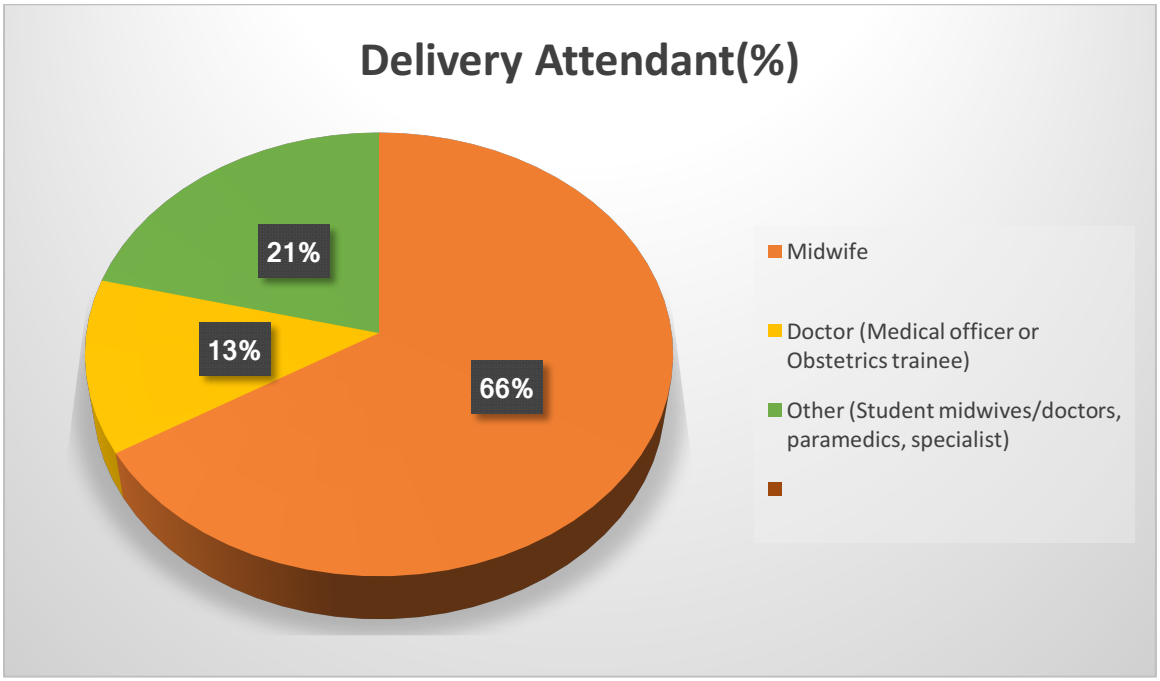


Figure IV: Mode of Delivery

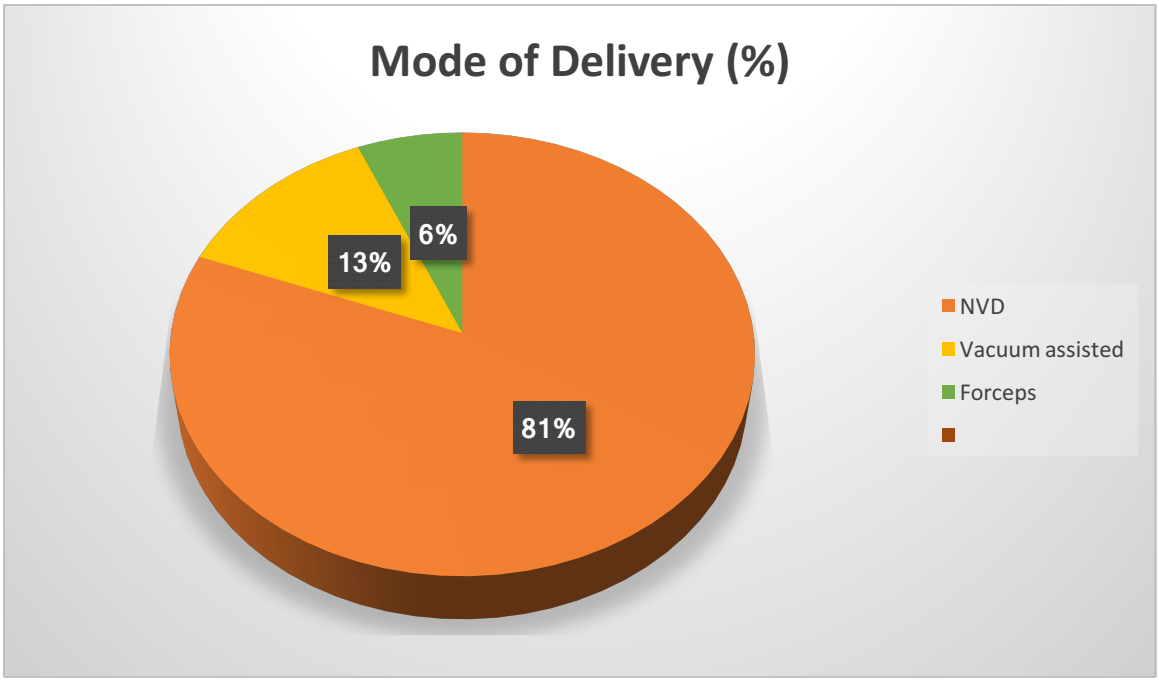


Figure V Shows the distribution of the depths of the tears in percentages. Not OASI refers to patients who were booked for repair of OASI, but examination in theatre revealed shallower tears. They are included in the analysis as many were booked and/or attended perineal clinic follow up. Figure VI indicates the method of repair used.

Only two of the participants were HIV positive, both with suppressed viral loads. A stat intraoperative dose of antibiotics as well as a postoperative course of antibiotics was given to 86,96% of participants. All but one participant received some form of antibiotics.

Figure V: Grade of Tear

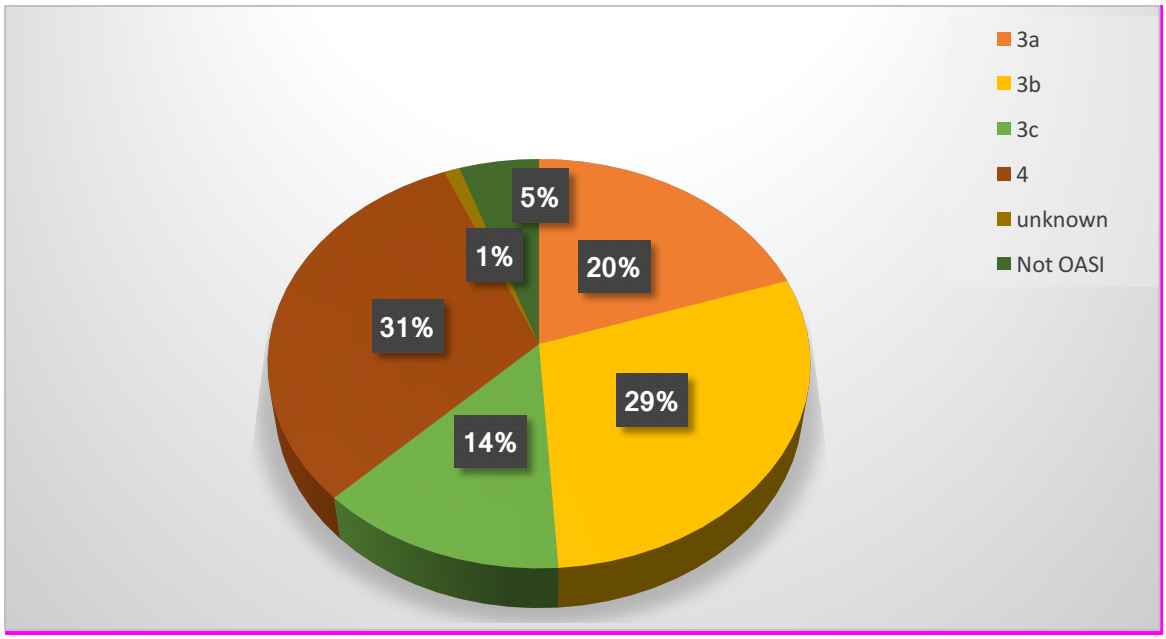
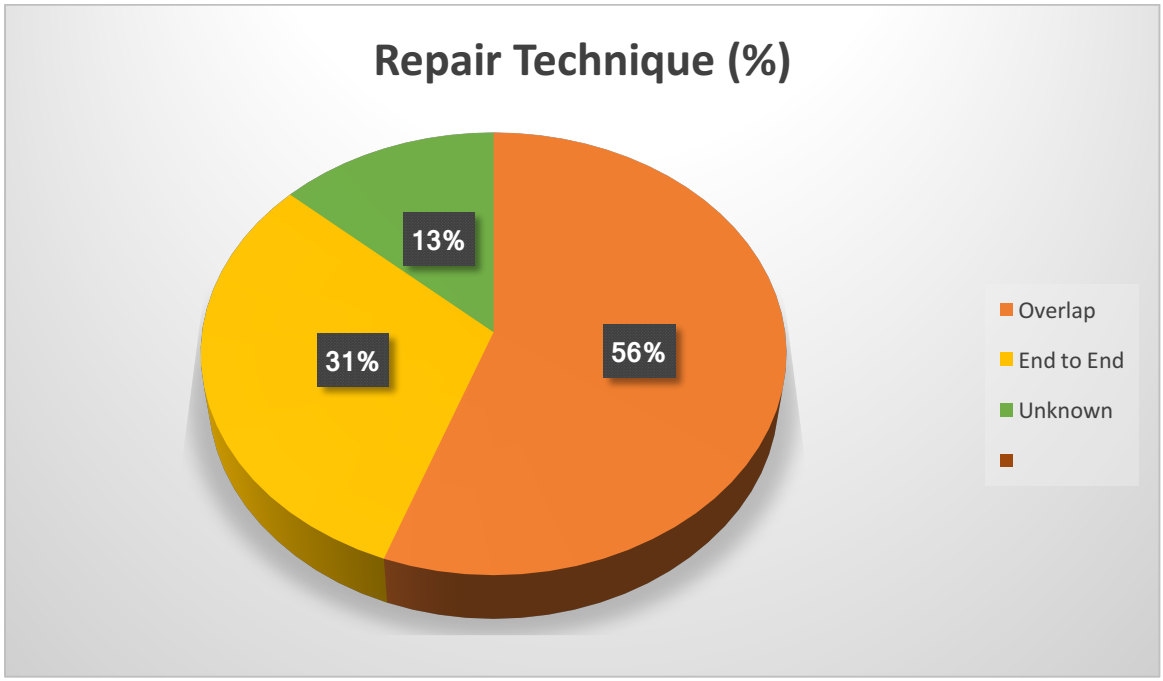


Figure VI: Technique of OASI repair



7.3 Incidence of OASI and follow up rate

Over the study period there were 43 270 vaginal deliveries[6] of which 374 sustained an OASI. This gives an incidence of 8.64 OASI per 1000 vaginal deliveries.

Only 97 of the 181 participants that were booked for follow up at GSH perineal clinic attended the clinic. The booking rate was thus 48.40% and the overall attendance rate 25.94% for the study period.

8. Discussion

The above data reveals an anal incontinence rate that is 1/3 of the rate seen internationally. This is on a background of an OASI rate similar to that seen worldwide with very poor follow up of only 25% of participants.

Wound dehiscence and infection are both recognised complications following OASI and are significant as poor healing can lead to development of chronic pain, sexual dysfunction, depression, faecal incontinence or fistula formation. [8] In our study the incidence of wound infection (3.26%) and wound dehiscence (6.67%) were similar to the 5-13% reported in international literature. [9]

The role of prophylactic antibiotics at repair remains unclear. Lewicky-Gaupp et al reports that any antibiotic use intrapartum for obstetric indications was associated with less wound complications, likely due to the fact that broad spectrum agents used will treat genitourinary organisms. In this study prophylactic use of antibiotics at the time of repair was associated with a small, non-statistical decrease in incidence of wound complications. [8] The randomised controlled trial by Duggal et al confirms this[10] while a retrospective chart review by Stock et al showed a higher incidence of wound complications in certain women, including those treated with antibiotics in the postpartum period,[9]. The authors postulate that the antibiotics were likely administered in order to treat existing infection. [9] In our study no association could be shown between the use of prophylactic antibiotics and wound complications. The majority of patients received some form of antibiotics in line with RCOG guidelines for repair of OASI. [1]

No association between HIV and wound complications could be shown in our study due to the low rate of HIV infection in the study population. Small study size and the poor follow up rate likely contributed to this.

Perineal pain is common in postpartum women, approximately 42% experiencing pain in the immediate post partum period, reducing to 22% and 10% at 8 and 12 weeks respectively.[11]A prospective cohort study by Andrews et al demonstrated significantly more perineal pain in participants with OASI than those with lesser degree perineal tears or intact perineum at both 7-10 days and 6-7 weeks postpartum.[4] Our study showed that a similar proportion (17.39%) of participants had perineal tenderness on examination. Constipation and pain on defaecation was reported in 10.87% and 11.96% of participants respectively which could be seen as substitute measures for perineal pain. These rates are half those reported by Andrews et al.

AI is defined as any involuntary loss of faeces or flatus that adversely affects a woman's quality of life or is a social or hygienic problem. This definition includes faecal urgency. [12] The incidence of AI following OASI has been reported to be between 27 and 57%. [3, 13-15] Evers et

al compared the incidence of AI in women with OASI to those who had shallower tears or caesarean delivery. In this study, they showed that women with OASI following instrumental delivery were most likely to suffer AI. The risk for AI was similar following vaginal instrumental delivery without OASI, normal vaginal delivery or caesarean section. They concluded from this study that OASI carries significant risk of AI 5-10 years post-delivery and that this has significant impact on their quality of life. [16]

The incidence of AI in our study was lower than international reports, only 10.87% for any form of incontinence. Faecal urgency was inadequately reported on and almost never mentioned in the clinical notes. Flatal incontinence was reported in 8.70% of patients and liquid stool incontinence in 3.33%. Only 4 participants (4.12%) reported incontinence to solid stool. This low rate could be due to the small sample size or the poor follow up rates, however, one would expect a woman with new onset of AI to attend her follow up appointment. The perineal clinic is staffed by the same doctors that run the tertiary urogynaecology service, so it is most likely that any woman presenting in the Metro West region with AI would be referred to the perineal clinic. Another explanation could be that the surgeons performing the repairs are well trained and that effective primary repairs are leading to lower rates of incontinence. These low rates of complications are particularly surprising in the context of an extremely busy obstetric service. Interestingly two participants reported incontinence to solid stool only without difficulty to control gas or liquid stool. Possible explanations for this are that flatus incontinence was not a new symptom and therefore not reported, and they might not have had an episode of diarrhoea in which to experience leakage of liquid stool.

A superior method of repair has not been conclusively identified. The RCOG recommends repair of full thickness external sphincter injuries using the overlap or end to end technique, with similar reported outcomes. Internal sphincter injuries and partial thickness external sphincter injuries should be repaired end to end. [1] A 2013 Cochrane review could not conclusively determine which method was superior. The Authors recommend that the practitioner perform overlap or end to end repair at their discretion. [17] Our study was not powered to detect superiority of repair technique; however, it would appear that the overlap technique achieved better results with regard to wound dehiscence. No advantage of either technique could be demonstrated with regards to AI. This analysis is confounded by depth of tear which influences repair technique.

The incidence of OASI in our study is comparable to that reported internationally at 0.864%. The patient profile in which OASI occurs is also comparable but this was not the subject of this study and contributory factors were not analysed.

The follow up rate in this population is very low at only 25.94% in total and 53.59% of patients that are booked for follow up. The most obvious contributory factors to this is that only half of the participants received an appointment for follow up after the repair. The fact that only half of those booked for the clinic actually attend could be due to a number of factors including poor explanation of the purpose and importance of follow up, distance to the clinic, transport issues, child care difficulties and possibly that the participant is well and doesn't feel the need to follow up.

9. Strengths and weaknesses

One of the main limitations of this study is the small sample size accompanied by the poor follow up rate which will clearly affect the data that is available for analysis. The retrospective nature of this study also limits the information that we can derive about the relationship of certain factors to the development of complications following OASI. As recognition and classification of OASI is dependent on clinical examination postpartum which may be performed by a junior member of staff, many OASIS might be missed as suggested by international literature which affects the accuracy of our results. Missing data and unanticipated confounding factors also limited the significance of the results. No standardised questionnaire was used in consultation with the participants, thus clinical notes which were sometimes incomplete were used for data collection.

In contrast, this is the first data available regarding the incidence of OASI as well as the incidence and nature of complications following primary repair within this setting. The identification of the poor follow-up rate among participants is important and will allow for the improvement of the booking system within our Maternity Hospitals. It should also encourage medical staff to improve communication and counselling of patients who have had a primary repair of an OASI. The use of an electronic system to capture appointment and attendance data ensures accuracy with regard to follow up data.

10. Conclusion

This is a small study with a poor follow up rate (25%) and it is thus difficult to make any firm conclusions about true complication rates of OASI and it is possible that women with complications were not able to attend their follow up or were not given an appointment. From the data we do have it appears that while the rate of OASI is similar to international figures, our rate of anal incontinence is lower than that reported elsewhere. This is the first study reporting this data in South Africa. The low incidence of complications is despite adverse conditions such as limited resources, theatre delays and the fact that repairs were mainly performed by specialists in training. This may be due to poor follow up and access to care. It has not been possible to show a causal relationship of any risk factors. This study informs of areas of clinical care where further investigation is needed.

11. References

1. Gynaecologists RCoOa. Greentop guideline no 29: Management of Third-and Fourth-degree perineal tears 2015. Available from: https://www.rcog.org.uk/globalassets/documents/guidelines/gtg-29.pdf.
2. Hirayama F, Koyanagi A, Mori R, et al. Prevalence and risk factors for third- and fourth-degree perineal lacerations during vaginal delivery: a multi-country study. BJOG. 2012;119(3):340-347.
3. Marsh F, Lynne R, Christine L, et al. Obstetric anal sphincter injury in the UK and its effect on bowel, bladder and sexual function. Eur J Obstet Gynecol Reprod Biol. 2011;154(2):223-227.
4. Andrews V, Thakar R, Sultan A, Jones P. Evaluation of postpartum perineal pain and dyspareunia—A prospective study. European Journal of Obstetrics & Gynecology and Reproductive Biology 2008;137:152-156.
5. van den Berg J, Jeffery S. Healing and functional outcomes after obstetric anal sphincter injury in HIV- positive vs HIV-negative patients. 2009. Masters Dissertation. Unpublished, Accesssed online via Open UCT.
6. National Perinatal Morbidity and Mortality Committee. Saving Babies 2014-2016: Triennial report on perinatal mortality in South Africa pg 15-22
7. Perry, S. et al. Prevalence of feacal incontinence in adults aged 40 years or more living in the community. Gut 2002; 50: 480-484
8. Lewicky-Gaupp C, Leader-Cramer A, Johnson LL, et al. Wound complications after obstetric anal sphincter injuries. Obstet Gynecol. 2015;125(5):1088-1093.
9. Stock L, Basham E, Gossett DR, Lewicky-Gaupp C. Factors associated with wound complications in women with obstetric anal sphincter injuries (OASIS). Am J Obstet Gynecol. 2013;208(4):327 e1-6.
10. Duggal N MC, Daniels K, Bujor A, Caughey AB, El-Sayed YY. Antibiotic Prophylaxis for Prevention of Postpartum Perineal Wound Complications: A Randomized Controlled Trial. Obstetrics and Gynaecology. 2008;111(6):1268-73
11. Abdool Z, Thakar R, Sultan AH. Postpartum female sexual function. Eur J Obstet Gynecol Reprod Biol. 2009;145(2):133-137.
12. LaCross A, Groff M, Smaldone A. Obstetric anal sphincter injury and anal incontinence following vaginal birth: a systematic review and meta-analysis. J Midwifery Womens Health. 2015;60(1):37-47.
13. Reid AJ, Beggs AD, Sultan AH, et al. Outcome of repair of obstetric anal sphincter injuries after three years. Int J Gynaecol Obstet. 2014;127(1):47-50.
14. Nichols C, Lamb E, Ramakrishnan V. Differences in outcomes after third-versus fourth-degree perineal laceration repair: A prospective study. AJOG. 2005;193:530-536.
15. Gjessing H, Backe B, Sahlin Y. Third degree obstetric tears; outcome after primary repair. Acta Obstet Gynecol Scand. 1998;77(7):736-740.
16. Evers EC, Blomquist JL, McDermott KC, Handa VL. Obstetrical anal sphincter laceration and anal incontinence 5-10 years after childbirth. AJOG. 2012;207(5):425 e1-6.
17. Fernando RJ, Sultan AH, Kettle C, Thakar R. Methods of repair for obstetric anal sphincter injury. Cochrane Database Syst Rev. 2013(12):CD002866.

12. Ethics Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E53-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6626
Email: shuretta.thomas@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

17 May 2018

HREC REF: 300/2018

Dr K Brouard
Obstetrics & Gynaecology
H-Floor, OMB

Dear Dr Brouard

PROJECT TITLE: A DESCRIPTION OF THE INCIDENCE AND NATURE OF COMPLICATIONS SEEN 6 WEEKS POST PRIMARY REPAIR OR OBSTETRIC ANAL SPHINCTER INJURY IN PATIENTS ATTENDING FOLLOW UP AT GROOTE SCHUUR PERINEAL CLINIC BETWEEN JANUARY 2014 AND DECEMBER 2015: A RETROSPECTIVE REVIEW (MMED CANDIDATE - DR C PAULSEN)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study subject to the following:

- The investigator will need to register the study on the NHRD database and will have to apply for permission to conduct the study at all 4 sites. Not only Groote Schuur Hospital as mentioned in the protocol.
- The investigator is advised to address the attrition that will result from missing data by including an algorithm indicating the number of potential subjects and then the numbers that are withdrawn with reasons and the actual number included in the final analysis.

Approval is granted for one year until the 30 May 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

The HREC acknowledge that the student, Dr Carrie Paulsen will also be involved in this study.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

13. Journal Guidelines

European Journal of Obstetrics & Gynecology and Reproductive Biology

Aims and scope

The ***European Journal of Obstetrics & Gynecology and Reproductive Biology: X*** is the open access mirror journal of The ***European Journal of Obstetrics & Gynecology and Reproductive Biology***. The ***European Journal of Obstetrics & Gynecology and Reproductive Biology*** is the leading general clinical journal covering all European countries. It publishes peer reviewed original research articles, expert opinions and reviews, and also news, book reviews and biographical, historical and educational articles. Fields covered include obstetrics, prenatal diagnosis, materno-fetal medicine, perinatology, general gynecology, gynecologic oncology, uro-gynecology, reproductive medicine, infertility, reproductive endocrinology, sexual medicine and reproductive ethics. It provides a forum for scientific and clinical professional communication in obstetrics and gynecology throughout Europe and the world.

Editorial policies
The following articles will be considered for publication: original research articles, review articles, expert opinions and letters to the Editor - brief communications (formerly case reports).

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis), that it is not under consideration for publication elsewhere, that its publication is approved by all Authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, without written consent of the Publisher.

Upon acceptance of an article, authors will be asked to complete an 'Exclusive License Agreement' (see more information on this). Permitted third party reuse of open access articles is determined by the author's choice of user license.

Author rights
As an author you (or your employer or institution) have certain rights to reuse your work. More information.

Articles must be written in English. Authors whose native language is not English are requested to have their manuscripts checked for linguistic correctness before submission.

English language help service
Upon request, Elsevier will direct authors to an agent who can check and improve the English of their paper (before submission). Please visit our Support Center for further information.

Online submission
Submission to the ***European Journal of Obstetrics & Gynecology and Reproductive***

Biology(EJOG) proceeds totally online. Paper copies of submissions are no longer acceptable. Via the web submission system for this journal, http://ees.elsevier.com/euro you will be guided stepwise through the creation and uploading of the various files. You will need to provide an electronic version of your manuscript and a separate electronic version of the abstract. You must select a category for your manuscript (see below). Once the uploading is done, the system automatically generates an electronic (PDF) proof, which is then used for reviewing. All correspondence, including the Editor's decision and request for revisions, will be by e-mail.

Peer Review

This journal operates a single blind review process. All contributions will be initially assessed by the editor for suitability for the journal. Papers deemed suitable are then typically sent to a minimum of two independent expert reviewers to assess the scientific quality of the paper. The Editor is responsible for the final decision regarding acceptance or rejection of articles. The Editor's decision is final. More information on types of peer review.

Author Agreement

An agreement by all authors (maximum 6 to 7) is required for submission. A statement to this effect is requested at submission stage.

Submission declaration and verification

Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. To verify originality, your article may be checked by the originality detection service Crossref Similarity Check.

Changes to Authorship

This policy concerns the addition, deletion, or rearrangement of author names in the authorship of accepted manuscripts:

Before the accepted manuscript is published in an online issue: Requests to add or remove an author, or to rearrange the author names, must be sent to the Journal Manager from the corresponding author of the accepted manuscript and must include: (a) the reason the name should be added or removed, or the author names rearranged and (b) written confirmation (e-mail, fax, letter) from all authors that they agree with the addition, removal or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed. Requests that are not sent by the corresponding author will be forwarded by the Journal Manager to the corresponding author, who must follow the procedure as described above. Note that: (1) Journal Managers will inform the Specialty Editors of any such requests and (2) publication of the accepted manuscript in an online issue is suspended until authorship has been agreed.

After the accepted manuscript is published in an online issue: Any requests to add, delete, or rearrange author names in an article published in an online issue will follow the same policies as noted above and result in a corrigendum.

Manuscript categories

During submission the author must select a category from the following list: Review Article, Research Article, Book Review, Letter to the Editor. In preparing submissions, authors should check the general requirements for the preparation of manuscripts (see below)

Review articles

As well as invited articles we welcome submitted reviews on topics of current interest in obstetrics and gynecology. Reviews are allowed a maximum of 3500 words (excluding title page, abstract and references), 10 figures and 10 tables. The reference list should not exceed 3 pages.

Expert Opinions

These are generally ″invited″ by the Editor-in-Chief but submission may be considered, with a maximum of 2000 words, 20 citations and 2 figures or 2 tables.

Research articles

For details, see below: ″General Requirements for the preparation of manuscripts″. There is a limit of 2500 words (excluding title page, abstract and references), 10 figures and 10 tables. The reference list should not exceed 3 pages.

Letters to the Editor are limited to a maximum of 600 words (excluding references, names and addresses of the signers, and the phrase "to the Editor"). Only one type of letter will be considered for publication:

Letter to the Editor - Brief Communication giving a brief case presentation or short report of a pertinent clinical observation. Please use the correct format following the criteria: max 600 words, max 5 references, max 1 table or 1 figure, no abstract, no keywords, no headings. The information must be presented as a true Letter, e.g. starting with ″Dear Editor, we found that... etc.″ Brief communications that do not meet this criteria will be returned to the author.

Announcements of major meetings and other significant activities should be sent to the Editor-in-Chief.

Editorial review process

Authors are responsible for following the criteria for the manuscript categories listed above before submitting the article to the Editorial Office. Articles not meeting these criteria will be rejected immediately without going through to peer review.

At submission authors will be asked to assign their article to a specialty subject area covered by the journal: obstetrics, maternal-fetal medicine, reproductive medicine and endocrinology, gynecology, gynecology oncology and urogynecology. All articles will undergo an initial review by an Advisory Board Editor expert in a particular specialty area. Articles will be assessed for:

- having sound methodological structure
- reporting novel results
- driving the field forward
- being within the scope of the journal
- being written clearly and understandably for a reviewer to do his/her job properly, and
- a potential for FastTrack review and publication

Articles not meeting these criteria will be rejected immediately without going through to full peer review.

Articles that have passed the initial review process are assigned by the Editorial Office to a Specialty Editor on the basis of the corresponding author's address. At least 2 independent reviewers are assigned per article for a systematic review of the article's aims, methodology, results and conclusions.

Following peer review, articles may be accepted without revision, accepted pending minor revision, not accepted but eligible for re-submission following major revision, or rejected. No more than two revision cycles are permitted per article - articles that after two revisions have still not adequately addressed the reviewers and Specialty Editors concerns will be rejected.

Authors are advised that during the review process the reviewers and/or the Specialty Editor may request additional statistical and language review. These articles will be reviewed by respectively an independent Statistical Advisor and Language Editor to the journal, either of whom may subsequently request additional changes prior to final acceptance of the manuscript.

Author's suggested reviewers
With their submitted manuscript, authors must provide the names and addresses of at least two reviewers for the consideration of the Editors in the Comments field during the online submission.

Human and non-human experimentation
The Editors require that manuscripts from a particular institution are submitted with the requisite authority (Ethical Committee). Reports of experiments on animals should state that the guidelines for the care and use of animals approved by the local institution were followed. For work described in your article involving human experimental investigations of any kind, must have been carried out in accordance with The Code of Ethics of the Declaration of Helsinki

Clinical Trials
The Editors of EJOG endorse and strongly encourage authors of reports of clinical trails to use the CONSORT checklist. The CONSORT E-Flowchart and a checklist of items to be included when reporting a cluster or randomised trial can both be found on CONSORT Checklist

Commercial potential
Authors who believe there may be commercial interest in the their article, e.g. for advertising or reprints, are requested to provide brief notes on the reason why this might be the case, and indicate the company or types of company that might be interested in this service.

Authorship
Each author (for manuscripts with 2 but not more than 6 to 7 authors) must qualify by having significantly participated in the study that is reported as well as made substantial contributions to the first concept and design or analysis and interpretation of data and second, writing the manuscript or revising it critically for content (see author agreement). Others contributing to the work should be recognised separately in an Acknowledgment.

General requirements for preparation of manuscripts
Manuscripts of research articles must be submitted in English and be structured in the

following order on a new page: title page, abstract, body of text, acknowledgments, references, legends for figures and tables.

Title page

The title page should contain in sequence the title (concise and suitable for indexing purposes), author line with first name, middle initials, and last name of each author; city(ies), state(s) and countries in which the study was conducted; divisional, or departmental, and institutional affiliations at the time the study was performed; name, address, telephone number, fax number and e-mail address of author responsible for correspondence concerning the manuscript if different from author to whom reprint requests are addressed.

Abstract page including key words/phrases

On manuscript page 3, type the abstract, double-spaced, with the required margins and headed by the title or the article and name(s) of the author(s. Below the abstract list 3 to 5 key words or short phrases for indexing purposes. A ***structured abstract*** (see description) is required for original research articles. A ***standard abstract*** is required for review articles and expert opinions (see description).

Structured abstract: A structured abstract, limited to 350 words, should be used for research articles and should contain the following major headings:

Objective(s), Study Design, Results and Conclusion(s). The Objective(s) reflects the purpose of the study, that is, the hypothesis that is being tested. The Study Design should include the setting for the study, the subjects (number and type), the treatment or intervention, and the type of statistical analysis. The Results include the outcome of the study and statistical significance if appropriate. The Conclusion(s) state(s) the significance of the results.

Standard abstract

A standard abstract is required for review articles and expert opinions and has no sub headings. It is limited to 500 words for reviews and 300 words for expert opinions.

Text

Only standard abbreviations may be used. Consult the Council of Biology Editors Style Manual or the AMA's Manual of
Style: http://healthlinks.washington.edu/hsl/styleguides/ama.html.

Abbreviations in the title are not acceptable. They should be avoided, if possible, in the abstract and keywords. In the text they should be kept to practical minimum. The full term for which an abbreviation stands should not precede its first use in the text unless it is a standard unit of measurement.

The generic, chemical or proprietary names of pharmaceuticals may be used. If the generic or chemical names are used, authors may, if they desire, insert the proprietary name in parentheses after the first mention in the text, with the name of the manufacturer and city and state.

Research articles are customarily organised into the following sections: In the ***Introduction***, state concisely the purpose and rationale for the study and cite only the most pertinent references as background. In the ***Materials and Methods*** section describe briefly the plan, the subjects, experimental animals or other species, material, and controls, the methods and procedures utilised, and the statistical method(s) employed. In the ***Results*** section present detailed findings. Include mentions of all tables, and/or figures. Figures and tables should supplement, not duplicate, the text; presentation of data in either one or the other will suffice.

In the ***Comment*** section state the importance and significance of your findings. Limit your opinions to those strictly indicated by the facts in your report. Compare your findings with those of others. No new data should be presented in this section.

Acknowledgments

Acknowledge only persons, institutes and agencies who have made substantial contributions to the study.

References

Adhere to the maximum number of references for each category of article (see above). Number references consecutively in the order in which they are mentioned in the text. Use the format of the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (Vancouver style) (N Engl J Med 1991: 324: 424-8). Journal titles should conform to the abbreviations used in Cumulated Index Medicus. If six or fewer authors, list all; if seven or more authors, list three then "et al".

Examples:

Journals

(1) Paterok EM, Roenthal H, Sabel M. Nipple discharge and abnormal galactogram. Results of a long-term study (1964-1999). Eur J Obstet Gynecol Reprod Biol 1993; 50: 227-34.

Books

(2) Brown SS, ed. Prenatal Care. Reaching Mothers, reaching infants. Washington: National Academy Press, 1998.

(3)[dataset] [3] Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. http://dx.doi.org/10.17632/xwj98nb39r.1.

Personal communications and unpublished data, if essential, may be used but not as numbered references. If they are used, they are to be referred to, within parentheses, at the appropriate location in the text. If used, the author(s) must obtain written and signed permission for their use from the individual being quoted. This signed permission must accompany the manuscript when it is submitted to the Editor. Published abstracts can be used as numbered references, however, reference to the complete published article is preferred.

Figures, Tables, Multi-media and Annexed files

Instructions on submitting these items online are provided under Artwork Instructions on the Journal's Instructions to Authors at http://www.elsevier.com/artworkinstructions.

The term ***figure*** includes all types of illustrations such as graphs, diagrams, photographs, flow charts and line drawings. A reasonable number of figures will be reproduced without charge. Figures must be cited consecutively in the text in Arabic numerals.

Colour figures will be published in print for an additional charge to the author of USD 1250.00 per page. The quoted charge is per page in colour, and as many as eight colour figures can be included on one page if the colour balance is appropriate. The colours used must be dark enough and of sufficient contrast for reproduction. With the exception of fluorescent colours, all colours can be reproduced in four colour figures. Figures submitted in colour will be published in colour online without charge.

Tables should be numbered in Arabic numerals. Each table must be cited in sequence at an appropriate point in the text. Titles should be brief yet indicate clearly the purpose or content of each table, and each column should be precisely defined by headings. Abbreviations and special designations should be explained in a footnote to the table. If a table or any part thereof has been taken from copyrighted material, a footnote to the table must give full credit to the original source.

Multi-media and annexed files are published only online. Multimedia files need to be sent to the Editorial Office on disk/cdrom or by e-mail, euro@elsevier.com

Video data
Elsevier accepts video material and animation sequences to support and enhance your scientific research. Authors who have video or animation files that they wish to submit with their article are strongly encouraged to include links to these within the body of the article. This can be done in the same way as a figure or table by referring to the video or animation content and noting in the body text where it should be placed. All submitted files should be properly labeled so that they directly relate to the video file's content. In order to ensure that your video or animation material is directly usable, please provide the files in one of our recommended file formats with a preferred maximum size of 50 MB. Video and animation files supplied will be published online in the electronic version of your article in Elsevier Web products, including ScienceDirect: http://www.sciencedirect.com. Please supply 'stills' with your files: you can choose any frame from the video or animation or make a separate image. These will be used instead of standard icons and will personalize the link to your video data. For more detailed instructions please visit our video instruction pages at http://www.elsevier.com/artworkinstructions. Note: since video and animation cannot be embedded in the print version of the journal, please provide text for both the electronic and the print version for the portions of the article that refer to this content.

AudioSlides
The journal encourages authors to create an AudioSlides presentation with their published article. AudioSlides are brief, webinar-style presentations that are shown next to the online article on ScienceDirect. This gives authors the opportunity to summarize their research in their own words and to help readers understand what the paper is about. More information and examples are available at http://www.elsevier.com/audioslides. Authors of this journal will automatically receive an invitation e-mail to create an AudioSlides presentation after acceptance of their paper.

RESEARCH DATA

This journal encourages and enables you to share data that supports your research publication where appropriate, and enables you to interlink the data with your published articles. Research data refers to the results of observations or experimentation that validate research findings. To facilitate reproducibility and data reuse, this journal also encourages you to share your software, code, models, algorithms, protocols, methods and other useful materials related to the project.

Below are a number of ways in which you can associate data with your article or make a statement about the availability of your data when submitting your manuscript. If you are sharing data in one of these ways, you are encouraged to cite the data in your manuscript and reference list. Please refer to the "References" section for more information about data

citation. For more information on depositing, sharing and using research data and other relevant research materials, visit the research data page.

Data linking

If you have made your research data available in a data repository, you can link your article directly to the dataset. Elsevier collaborates with a number of repositories to link articles on ScienceDirect with relevant repositories, giving readers access to underlying data that gives them a better understanding of the research described.

There are different ways to link your datasets to your article. When available, you can directly link your dataset to your article by providing the relevant information in the submission system. For more information, visit the database linking page .

For supported data repositories a repository banner will automatically appear next to your published article on ScienceDirect.

In addition, you can link to relevant data or entities through identifiers within the text of your manuscript, using the following format: Database: xxxx (e.g., TAIR: AT1G01020; CCDC: 734053; PDB: 1XFN).

Mendeley Data

This journal supports Mendeley Data, enabling you to deposit any research data (including raw and processed data, video, code, software, algorithms, protocols, and methods) associated with your manuscript in a free-to-use, open access repository. During the submission process, after uploading your manuscript, you will have the opportunity to upload your relevant datasets directly to ***Mendeley Data***. The datasets will be listed and directly accessible to readers next to your published article online.

For more information, visit the Mendeley Data for journals page.

Data statement

To foster transparency, we encourage you to state the availability of your data in your submission. This may be a requirement of your funding body or institution. If your data is unavailable to access or unsuitable to post, you will have the opportunity to indicate why during the submission process, for example by stating that the research data is confidential. The statement will appear with your published article on ScienceDirect. For more information, visit the Data statement page.

Permissions

Photographs of identifiable persons must be accompanied by signed releases. If not, all recognisable features must be masked.

If excerpts from other copyrighted works are included (direct quotations, tables or figures) the Author(s) must obtain written permission from the copyright owners and credit source(s) in the article along with complete reference information. Elsevier has pre-printed forms for use by Authors in these cases: contact Elsevier's Rights Department, Philadelphia, PA, USA: phone (+1) 215 239 3804, fax (+1) 215 239 3805, e-mail healthpermissions@elsevier.com.

Requests may also be completed online via the Elsevier homepage http://www.elsevier.com/locate/permissions.

Conflict of interest
All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Role of the funding source
All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the collection, analysis and interpretation of data and in the writing of the manuscript. If the study sponsors had no such involvement, the authors should so state.

Page proofs
One set of pdf proofs will be sent to the authors to be carefully checked for printer's errors. Changes or additions to the edited manuscript will ***not*** be allowed at the this stage. Authors are requested to return the corrected proofs immediately by fax or e-mail as instructed.

Reprints
The corresponding author, at no cost, will be provided with a PDF file of the article via e-mail. The PDF file is a watermarked version of the published article and includes a cover sheet with the journal cover image and a disclaimer outlining the terms and conditions of use. Additional paper offprints can be ordered by the authors. An order form with prices will be sent to the corresponding author. This must be completed and returned to the publisher with the proofs. Orders for reprints cannot be accepted at a later date because the reprints are made at the time the journal is printed.

Business communications
Communications of a business nature should be addressed to: The Publisher, ***European Journal of Obstetrics & Gynecology and Reproductive Biology***, Elsevier B.V., Health Sciences, PO Box 993, 1000 AZ Amsterdam, The Netherlands, Tel: (+31) 20 485 3007; Fax: (+31) 20 485 3249

Citations
The ***European Journal of Obstetrics & Gynecology and Reproductive Biology*** is cited in: Current Contents (Clinical Medicine), Index Medicus (MEDLINE), Excerpta Medica (EMBASE), Pascal et Francis (INIST-CNRS), Elsevier BIOBASE/Current Awareness in Biological Sciences.

Page charges
The ***European Journal of Obstetrics & Gynecology and Reproductive Biology*** has no page charges.

Table of Contents and Abstracts of published articles are freely accessible at http://www.sciencedirect.com/science/journal/03012115.

Funding body agreements and policies
Elsevier has established a number of agreements with funding bodies which allow authors to

comply with their funder's open access policies. Some funding bodies will reimburse the author for the gold open access publication fee. Details of existing agreements are available online.

Open access
This is an open access journal: all articles will be immediately and permanently free for everyone to read and download. To provide open access, this journal has an open access fee (also known as an article publishing charge APC) which needs to be paid by the authors or on their behalf e.g. by their research funder or institution. Permitted third party (re)use is defined by the following Creative Commons user licenses:

Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND): For non-commercial purposes, lets others distribute and copy the article, and to include in a collective work (such as an anthology), as long as they credit the author(s) and provided they do not alter or modify the article.

Creative Commons Attribution (CC BY):Lets others distribute and copy the article, create extracts, abstracts, and other revised versions, adaptations or derivative works of or from an article (such as a translation), include in a collective work (such as an anthology), text or data mine the article, even for commercial purposes, as long as they credit the author(s), do not represent the author as endorsing their adaptation of the article, and do not modify the article in such a way as to damage the author's honor or reputation.

Open Access Fee
The gold open access publication fee for this journal is *USD 2500*, excluding taxes. Learn more about Elsevier's pricing policy: https://www.elsevier.com/openaccesspricing

*Submit your Article*Please submit your article via https://ees.elsevier.com/euro/default.asp. Please note that one, unified editorial team manages the peer-review for both The ***European Journal of Obstetrics & Gynecology and Reproductive Biology*** and The ***European Journal of Obstetrics & Gynecology and Reproductive Biology: X*** using the same submission system